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111TH CONGRESS
1ST SESSION

H. R. 2813

To establish a national knee and hip replacement registry.

IN THE HOUSE OF REPRESENTATIVES

JUNE 10, 2009

Mr. PASCRELL (for himself and Mr. DOGGETT) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish a national knee and hip replacement registry.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''National Knee and Hip Replacement Registry Act of 2009''.

SEC. 2. ESTABLISHMENT.

(a) IN GENERAL.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish within the Agency for Healthcare Research and Quality a national knee and hip

replacement registry (referred to in this Act as the ''registry'') for the purpose of identifying predictors (including patient co-morbidities, conditions, and characteristics; features of the prostheses; and surgical technique) that may lead to poor outcomes in knee and hip replacement surgeries in order to assist health care providers in medical and surgical decision-making, improve patient care and outcomes generally, detect poorly performing prostheses and surgical techniques, and reduce the number of knee and hip replacement revision surgeries required nationwide.

(b) POLICIES AND PROCEDURES.—Such registry shall be subject to the policies and procedures developed under section 3(a).

SEC. 3. KNEE AND HIP REPLACEMENT REGISTRY POLICIES AND PROCEDURES.

(a) POLICIES AND PROCEDURES.—Not later than 3 years after the date of the enactment of this Act, the Administrator of the Centers for Medicare and Medicaid Services, in coordination with the Director of the Agency for Healthcare Research and Quality, shall develop policies and procedures for the development and maintenance of the registry under section 2. The policies and procedures shall address—

(1) the scope of data collection to be conducted by the registry to conform with the purpose of the registry as defined in section 2;

(2) the core data set to be used by the registry;

(3) policies to be used by the registry to—

(A) ensure scientific rigor in data collection and analysis;

(B) avoid bias in the analysis of data;

(C) ensure that analysis of the data collected can be generalizable to the population of people getting knee and hip replacements;

(D) protect, to the extent practicable, trade secrets of manufacturers of knee and hip replacement prostheses and related products; and

(E) protect patient privacy; and

(4) guidelines for data collection that—

(A) incorporate, to the extent practicable, the recommendations and feedback of stakeholders, including—

(i) orthopedic practitioners and providers, such as hospitals, surgeons, nurses, and other practitioners and providers;

(ii) manufacturers of knee and hip replacement prostheses and related products; and

(iii) patient and consumer groups;

(B) balance the importance and usefulness of potential findings resulting from the collection of data by the registry with the feasibility and administrative burden on collecting such data;

(C) allow the registry to use, to the extent practicable, data that is collected through existing Federal reporting requirements; and

(D) rely, to the extent practicable, on the voluntary submission of data on both Medicare and non-Medicare patients by practitioners and providers.

(b) INTERAGENCY COOPERATION.—In developing of the policies and procedures under subsection (a), the Administrator of the Centers for Medicare and Medicaid Services shall consult with the heads of the Agency for Healthcare Research and Quality, the Food and Drug Administration, the National Institutes of Health, and the Office of the National Coordinator for Health Information Technology.

SEC. 4. ACTIVITIES OF THE REGISTRY.

(a) DATA COLLECTION AND STORAGE.—Beginning not later than 5 years after the date of the enactment of this Act, the head of the registry shall collect and store data related to knee and hip replacements (including information related to prosthetic devices and surgical procedures consistent with the policies and procedures under section 3(a) in the registry established under subsection (a) of section 2).

(b) DATA ANALYSIS.—The head of the registry shall conduct data analysis to fulfil the purpose of the registry under section 2.

(c) ACCESS TO DATA.—

(1) PROVISION OF DATA TO PROVIDERS.—At least one time per year, beginning not later than 6 years after the date of enactment of this Act, the head of the registry shall provide data to health care providers to allow them to evaluate their performance, relative to their peers, in—

(A) conducting knee and hip replacement surgeries; and

(B) providing care related to such surgeries.

(2) PROVISION OF DATA TO MANUFACTURERS.—At least one time per year, beginning not later than 7 years after the date of the enactment

of this Act, the head of the registry shall provide data to manufacturers of knee and hip replacement prostheses and related products to allow such manufacturers to evaluate the safety and performance of their products relative to similar products available on the market.

(3) USE OF REGISTRY BY RESEARCHERS.—The head of the registry shall develop a process to allow outside researchers to apply to use individually identifiable data that is contained in the registry to conduct longitudinal studies consistent with the purpose of the registry under section 2.

(d) COORDINATION WITH FDA, NIH, AND OTHER HHS ENTITIES.—To avoid duplication in data collection and analysis, the head of the registry shall coordinate activities of the registry with—

(1) comparative effectiveness research conducted by—

(A) the Agency for Healthcare Research and Quality;

(B) the National Institutes of Health; and

(C) the Office of the Secretary of Health and Human Services; and

(2) postmarket surveillance activities conducted by the Food and Drug Administration.

(e) COLLECTION OF REGISTRY INFORMATION FROM FEDERAL DEPARTMENTS AND AGENCIES.—

(1) REQUESTS BY THE REGISTRY.—The head of the registry may request data from Federal departments and agencies if the collection of such data by the entity established under section 2 conforms with the policies and procedures under section 3.

(2) AGENCY OBLIGATIONS.—Federal departments and agencies shall provide relevant data to the registry at the request of the head of the registry under paragraph (1).

(f) PUBLIC FEEDBACK.—Not later than 2 years after beginning to collect data under subsection (a) and at the end of each subsequent 2-year period, in order to enhance the registry's ability to achieve the purpose of the registry under section 2 and update policies and procedures under section 3, the head of the registry, in consultation with the Center for Medicare and Medicaid Services, the Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the National Coordinator of Health Information Technology, and the National Institutes of Health shall seek feedback from—

(1) orthopedic providers, such as hospitals, surgeons, nurses, and other practitioners;

(2) manufacturers of knee and hip replacement prostheses and related products;

(3) patient and consumer groups; and

(4) public health experts and epidemiologist.

(g) PUBLIC REPORT.—Beginning not later than six years after enactment, the head of the registry shall publish and make publically available an annual report that contains—

(1) an overview of the data collected by under subsection (a);

(2) the findings resulting from any analysis of such data conducted by the registry; and

(3) any other information that the head of the registry determines is appropriate.

SEC. 5. SAFETY MONITORING AND REPORTING.

(a) SAFETY MONITORING.—The Agency for Healthcare Research and Quality and the Food and Drug Administration shall use the data in the registry and any analysis of such data conducted by the registry or by other entities to monitor and evaluate the safety of knee and hip replacement procedures and devices.

(b) REPORT.—Not later than 6 years after the date of the enactment of this Act and annually thereafter, the Agency for Healthcare Research and Quality, in consultation with Food and Drug Administration, shall submit a

report to the Secretary of Health and Human Services and Congress containing recommendations on changes in policy and health care provider practices that could enhance the safety of knee and hip replacements.

SEC. 6. DEPARTMENT OF HEALTH AND HUMAN SERVICES COLLECTION OF INFORMATION FROM PROVIDERS AND OTHER ENTITIES.

(a) MODIFICATION OF REQUIRED DATA.—The Secretary of Health and Human Services may modify the information required to be reported under administrative data sets under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) (including data that is required to be submitted by Medicare Advantage organizations and quality improvement organizations) to the extent the Secretary, in consultation with the head of the registry, determines that the modification would result in the reporting of information that would be useful in carrying out the purpose of the registry under section 2.

(b) CONDITION OF PARTICIPATION.—In the case that two consecutive reports submitted under section 7(a) conclude that the level of provider participation in the registry is insufficient to achieve the purpose of the registry under section 2, the Secretary of Health and Human Services may require providers of services (as defined under section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)))

and physicians and other suppliers (as defined in subsections (r) and (d) of section 1861 of the Social Security Act (42 U.S.C. 1395x(r) and (d)), respectively) to report relevant information directly to the registry as a condition of participation in the Medicare program under section 1866 and 1842(h) of the Social Security Act (42 U.S.C. 1395cc and 42 U.S.C. 1395u(h)), respectively.

SEC. 7. OVERSIGHT OF THE REGISTRY.

(a) IN GENERAL.—Not later than 1 year after the date the registry begins collecting data under section 4(a) and the end of each subsequent 2-year period, the Comptroller General of the United States shall submit to Congress a report on the progress of the registry in achieving the purposes of the registry under section 2.

(b) INFORMATION ON PROVIDER PARTICIPATION.—The report under subsection (a) shall include information on the number of providers participating in the registry and an analysis of whether that level of provider participation is sufficient to achieve the purposes of the registry under section 2.

SEC. 8. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act, such sums as are necessary for fiscal years 2010 through 2019.

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